

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION**

INDIVIOR INC. *f/k/a* RECKITT BENCKISER  
PHARMACEUTICALS INC., and  
AQUESTIVE THERAPEUTICS, INC. *f/k/a*  
MONOSOL RX, LLC,

Plaintiffs

v.

BIODELIVERY SCIENCES  
INTERNATIONAL, INC.,

Defendant

Civil Action No. 5:15-CV-00350-D

**PROTECTIVE ORDER REGARDING THE DISCLOSURE AND USE  
OF DISCOVERY MATERIALS**

Plaintiffs Indivior Inc. and Aquestive Therapeutics, Inc. (“Plaintiffs”) and Defendant BioDelivery Sciences International, Inc. (“Defendant”) (collectively, the “Parties”) anticipate that discovery in E.D. N.C. Civil Action No. 5:15-CV-00350-D, which is captioned above, may necessarily involve the disclosure of certain documents, things, and information in the possession, custody or control of a Party or a non-party that constitute or contain trade secrets or other confidential research, development, manufacture, regulatory, financial, marketing or other competitive information within the meaning of Rule 26(c)(1)(G) of the Federal Rules of Civil Procedure.

The Parties have in good faith conferred and have agreed upon the terms of a Consent Protective Order Regarding the Disclosure and Use of Discovery Materials (“Order” or “Protective Order”) setting forth the conditions for treating, obtaining, and using such information. The Parties stipulate, pursuant to Rule 26(c) of the Federal Rules of Civil Procedure and L. Civ. R. 5.3(b), subject to the approval of the Court, to the following Confidentiality Order:

**1. PURPOSE AND LIMITATIONS**

(a) Protected Material designated under the terms of this Protective Order shall be used by Parties solely in this Action, and shall not be used directly or indirectly for any other purpose whatsoever.

(b) Designations under this Order shall be made with care and shall not be made absent a good faith belief that the designated material satisfies the criteria set forth below. If it comes to a Producing Party’s attention that designated material does not qualify for protection at all, or does not qualify for the level of protection initially asserted, the Producing Party must promptly notify the Receiving Party that it is withdrawing or changing the designation.

(c) This Order is not intended to address discovery objections to produce, answer, or respond on the grounds of attorney-client privilege or work product immunity, or to preclude either

Party from seeking further relief or confidentiality orders from the Court as may be appropriate under the Federal Rules of Civil Procedure or the Local Rules of the Eastern District of North Carolina.

## **2. DEFINITIONS**

(a) This “Action” shall refer E.D. N.C. Civil Action No. 5:15-CV-00350-D, which is captioned above, and shall not include any other case or matters regardless of whether they are related.

(b) “Discovery Material” means all items or information, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced, disclosed, or generated in connection with discovery in this Action.

(c) “Outside Counsel” means (i) outside counsel who appear on the pleadings as counsel for a Party in this Action and (ii) partners, associates, paralegals, and staff of such counsel to whom it is reasonably necessary to disclose the information for this Action.

(d) “Party” means either of the two Plaintiffs or the Defendant in this Action, including all of their officers, directors, employees, consultants, retained experts, and outside counsel and their support staffs.

(e) “Producing Party” means any Party that discloses or produces any Discovery Material in this Action.

(f) “Protected Material” means any Discovery Material that is designated as “CONFIDENTIAL” or “HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES ONLY” as provided for in this Order. Protected Material shall not include: (i) advertising materials that have been actually published or publicly disseminated; and (ii) materials that show on their face they have been disseminated to the public.

(g) “Receiving Party” means any Party who receives Discovery Material from a Producing Party.

**3. COMPUTATION OF TIME**

All references to “days” in this Confidentiality Order shall be construed as calendar days and shall be calculated pursuant to Federal Rule of Civil Procedure 6(a), unless otherwise specifically indicated.

**4. SCOPE**

(a) The protections conferred by this Order cover Discovery Material as addressed herein, and also apply to any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof, and testimony, conversations, or presentations by Parties or their counsel in court or in other settings that might reveal Protected Material.

(b) Nothing in this Protective Order shall prevent or restrict a Producing Party’s own disclosure or use of its own Protected Material for any purpose, and nothing in this Order shall preclude any Producing Party from showing its Protected Material to an individual who prepared the Protected Material.

(c) Nothing in this Order shall be construed to prejudice any Party’s right to use any Protected Material in any court filing or presentation in this Action either with the consent of the Producing Party or pursuant the procedure set forth in Section 13 below.

(d) This Order is without prejudice to the right of any Party to seek further or additional protection of any Discovery Material or to modify this Order in any way, including, without limitation, an order that certain matter not be produced at all.

**5. DURATION**

Even after the termination of this Action, the confidentiality obligations imposed by this Order shall remain in effect until a Producing Party agrees otherwise in writing or a court order otherwise directs.

**6. ACCESS TO AND USE OF PROTECTED MATERIAL**

(a) Basic Principles. All Protected Material shall be used solely for this Action, and not for any other purpose whatsoever, including without limitation any other litigation, patent prosecution or acquisition, patent reexamination or reissue proceedings, or any business or competitive purpose or function. Protected Material shall not be distributed, disclosed or made available to anyone except as expressly provided in this Order.

(b) Legal Advice Based on Protected Material. Nothing in this Protective Order shall be construed to prevent counsel from advising their clients with respect to this Action based in whole or in part upon Protected Material, provided counsel does not disclose the Protected Material itself.

(c) Limitations. Nothing in this Order shall restrict in any way a Producing Party's use or disclosure of its own Protected Material. Nothing in this Order shall restrict in any way the use or disclosure of Discovery Material by a Receiving Party: (i) that is or has become publicly known through no fault of the Receiving Party; (ii) that is lawfully acquired by or known to the Receiving Party independent of the Producing Party; (iii) that was previously produced, disclosed and/or provided by the Producing Party to the Receiving Party or a non-party without an obligation of confidentiality and not by inadvertence or mistake; (iv) with the consent of the Producing Party; or (v) pursuant to order of the Court.

**7. DESIGNATING PROTECTED MATERIAL**

(a) Available Designations. Any Producing Party may designate Discovery Material with any of the following designations, provided that it meets the requirements for such designations as provided for herein: “CONFIDENTIAL,” and “HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES ONLY.”

(b) Written Discovery and Documents and Tangible Things. Written discovery, documents (which include “electronically stored information,” as that phrase is used in Rule 34 of Federal Rule of Civil Procedure), and tangible things that meet the requirements for the confidentiality designations listed in Paragraph 7(a) may be so designated by placing the appropriate designation on every page of the written material prior to production. For digital files being produced, the Producing Party may mark each viewable page or image with the appropriate designation, and mark the medium, container, and/or communication in which the digital files were contained. In the event that original documents are produced for inspection, the original documents shall be presumed “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” during the inspection and re-designated, as appropriate during the copying process.

(c) Native Files. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Order by appending to the file names or designators information indicating whether the file contains “CONFIDENTIAL,” “HIGHLY CONFIDENTIAL - ATTORNEYS’ EYES ONLY” material, or shall use any other reasonable method for so designating Protected Materials produced in electronic format. When electronic files or documents are printed for use at deposition, in a court proceeding, or for provision in printed form to a pre-approved expert or consultant, the party printing the electronic files or documents shall affix a legend to the printed document corresponding to the

designation of the Designating Party and including the production number and designation associated with the native file.

(d) Depositions and Testimony. Parties or testifying persons or entities may designate depositions and other testimony with the appropriate designation by indicating on the record at the time the testimony is given, or by sending written notice of how portions of the transcript of the testimony are designated within thirty (30) days of receipt of the transcript of the testimony. If no indication on the record is made, all information disclosed during a deposition shall be deemed “HIGHLY CONFIDENTIAL – ATTORNEYS’ EYES ONLY” until the time within which it may be appropriately designated as provided for herein has passed. Any Party that wishes to disclose the transcript, or information contained therein, may provide written notice of its intent to treat the transcript as non-confidential, after which time, any Party that wants to maintain any portion of the transcript as confidential must designate the confidential portions within fourteen (14) days, or else the transcript may be treated as non-confidential. Any Protected Material that is used in the taking of a deposition shall remain subject to the provisions of this Protective Order, along with the transcript pages of the deposition testimony dealing with such Protected Material. In such cases the court reporter shall be informed of this Protective Order and shall be required to operate in a manner consistent with this Protective Order. In the event the deposition is videotaped, the original and all copies of the videotape shall be marked by the video technician to indicate that the contents of the videotape are subject to this Protective Order, substantially along the lines of “This videotape contains confidential testimony used in this case and is not to be viewed or the contents thereof to be displayed or revealed except pursuant to the terms of the operative Protective Order in this Action or pursuant to written stipulation of the parties.” Counsel for any Producing Party shall have the right to exclude from oral depositions, other than the deponent, deponent’s counsel, the reporter and videographer (if any), any person who is not authorized by this Protective Order to receive

or access Protected Material based on the designation of such Protected Material. Such right of exclusion shall be applicable only during periods of examination or testimony regarding such Protected Material.

**8. DISCOVERY MATERIAL DESIGNATED AS “CONFIDENTIAL”**

(a) A Producing Party may designate Discovery Material as “CONFIDENTIAL” if it contains or reflects confidential, proprietary, and/or commercially sensitive information.

(b) Unless otherwise ordered by the Court, Discovery Material designated as “CONFIDENTIAL” may be disclosed only to the following:

(i) The Receiving Party’s Outside Counsel and any copying or litigation support service providers working under the direction and authority of such Outside Counsel.

(ii) Not more than three (3) representatives of the Receiving Party who are officers or employees of the Receiving Party, who may be, but need not be, in-house counsel for the Receiving Party, as well as their immediate paralegals and staff, to whom disclosure is reasonably necessary for this Action, provided that each such person has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(iii) Any outside expert or consultant retained by the Receiving Party to assist in this Action, or retained by a Party in connection with this Action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; and (b) such expert or consultant is not a current or former officer, director, or employee of a Party or a current officer, director, or employee of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this Action;



(v) The Court and court personnel in this Action;

(vi) Graphics, translation, design, and/or trial consulting personnel, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(vii) Any mediator who is assigned to hear this Action, and the mediator's staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(viii) Any other person with the prior written consent of the Producing Party.

**9. DISCOVERY MATERIAL DESIGNATED AS "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY"**

(a) A Producing Party may designate Discovery Material as "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" if it contains or reflects information that is extremely confidential and/or sensitive in nature and the Producing Party reasonably believes that the disclosure of such Discovery Material is likely to cause economic harm or significant competitive disadvantage to the Producing Party. The Parties agree that the following information, if non-public, shall be presumed to merit the "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" designation: trade secrets, pricing information, financial data, sales information, sales or marketing forecasts or plans, business plans, sales or marketing strategy, product development information, testing documents, employee information, and other non-public information of similar competitive and business sensitivity.

(b) Unless otherwise ordered by the Court, Discovery Material designated as "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" may be disclosed only to:

(i) The Receiving Party's Outside Counsel and any copying or litigation support service providers working under the direction and control of such Outside Counsel.

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this Action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current or former officer, director, or employee of a Party or a current officer, director, or employee of a competitor of a Party, nor anticipated at the time of retention to become an officer, director, or employee of a Party or of a competitor of a Party; and (c) such expert or consultant is not involved in competitive decision-making on behalf of a Party or a competitor of a Party, defined as activities, association, and relationship with a client that involve advice and participation in any or all of the client's decisions (pricing, product design, etc.) made in light of similar or corresponding information about a competitor;

(iii) Court reporters, stenographers and videographers retained to record testimony taken in this Action;

(iv) The Court and court personnel in this Action;

(v) Graphics, translation, design, and/or trial consulting personnel, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(vi) Any mediator who is assigned to hear this Action, and mediator's staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(vii) Any other person with the prior written consent of the Producing Party.

## **10. NOTICE OF DISCLOSURE**

(a) Prior to disclosing any Protected Material to any person described in Paragraphs 8(b)(iii) or 9(b)(ii) (referenced below as “Person”), the Party seeking to disclose such information shall provide the Producing Party with written notice that includes:

- (i) the name of the Person;
- (ii) an up-to-date curriculum vitae of the Person; and
- (iii) the present employer and title of the Person.

(b) Within seven (7) days of receipt of the disclosure of the Person, the Producing Party or Parties may object in writing to the Person for good cause. In the absence of an objection at the end of the seven (7) day period, the Person shall be deemed approved under this Protective Order. There shall be no disclosure of Protected Material to the Person prior to expiration of this seven (7) day period. If the Producing Party objects to disclosure to the Person within such seven (7) day period, the Parties shall meet and confer via telephone or in person within two (2) days following the objection and attempt in good faith to resolve the dispute on an informal basis. If the dispute is not resolved, the Party objecting to the disclosure will have five (5) days from the date of the meet and confer to seek relief from the Court. If relief is not sought from the Court within that time, the objection shall be deemed withdrawn. If relief is sought, designated materials shall not be disclosed to the Person in question until the Court resolves the objection.

(c) For purposes of this section, “good cause” shall include an objectively reasonable concern that the Person will, advertently or inadvertently, use or disclose Discovery Materials in a way or ways that are inconsistent with the provisions contained in this Order.

(d) Prior to receiving any Protected Material under this Order, the Person must execute a copy of the “Agreement to Be Bound by Protective Order” (Exhibit A hereto) and serve it on all Parties.

## **11. CHALLENGING DESIGNATIONS OF PROTECTED MATERIAL**

(a) A Party shall not be obligated to challenge the propriety of any designation of Discovery Material under this Order at the time the designation is made, and a failure to do so shall not preclude a subsequent challenge thereto.

(b) Any challenge to a designation of Discovery Material under this Order shall be written, shall be served on Outside Counsel for the Producing Party, shall particularly identify the documents or information that the Receiving Party contends should be differently designated, and shall state the grounds for the objection. Thereafter, further protection of such material shall be resolved in accordance with the following procedures:

(i) The objecting Party shall have the burden of conferring either in person, in writing, or by telephone with the Producing Party claiming protection (as well as any other interested party) in a good faith effort to resolve the dispute. The Producing Party shall have the burden of justifying the disputed designation;

(ii) Failing agreement, the Receiving Party may bring a motion to the Court for a ruling that the Discovery Material in question is not entitled to the status and protection of the Producing Party's designation. The Parties' entry into this Order shall not preclude or prejudice either Party from arguing for or against any designation, establish any presumption that a particular designation is valid, or alter the burden of proof that would otherwise apply in a dispute over discovery or disclosure of information;

(iii) Notwithstanding any challenge to a designation, the Discovery Material in question shall continue to be treated as designated under this Order until one of the following occurs: (a) the Party who designated the Discovery Material in question withdraws such designation in writing; or (b) the Court rules that the Discovery Material in question is not entitled to the designation.

## **12. FILING PROTECTED MATERIAL**

(a) In accordance with § V.G(1)(e) of the Court's Electronic Case Filing Administrative Policies and Procedures Manual ("Policy Manual"), in the event that a filing Party seeks to file materials that have been designated "CONFIDENTIAL," or "HIGHLY CONFIDENTIAL — OUTSIDE ATTORNEYS' EYES ONLY" by another Party, individual or non-party, the filing Party shall provisionally file the materials under seal in accordance with Local Civil Rule 79.2, with notice served on the designating Party, individual or non-party. In accordance § V.G(1)(e)(i), the filing Party will submit a notice of filing in lieu of a motion to seal and the filing of these third party material under seal, by itself, shall not be binding on the Court. However, documents submitted under seal in accordance with § V.G(1)(e) will remain under seal pending the Court's ruling on the motion to seal. Within seven (7) days after such notice, the designating Party, individual or non-party shall file a motion to seal and supporting memorandum in accordance with § V.G(1) of the Policy Manual.

(b) Where a Party seeks to submit documents to the Court which have been designated "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL — OUTSIDE ATTORNEYS' EYES ONLY" by the submitting Party, the submitting Party may, in its discretion, bring a motion to file such documents under seal pursuant to Local Civil Rules 7.1, 79.2, and § V.G(1) of the Court's Policy Manual. Where a submitting Party intentionally declines to seek an order sealing documents submitted to the Court designated as containing its own Protected Material, the submitted material will no longer qualify for protection and subsequent treatment as containing Protected Material under this Protective Order.

(c) In accordance with the Section G of the Policy Manual, each time a Party seeks to file under seal to protect its own Protected Material, said Party shall accompany the request with a motion to seal. The motion to seal may be filed without a supporting memorandum only if the filing Party can cite a statute or rule (federal, local or standing order) that requires the filing to be sealed. Absent

such authority, the filing Party must submit a supporting memorandum that specifies: (i) the exact document or item, or portions thereof, for which filing under seal is requested; (ii) how such request to seal overcomes the common law or the First Amendment presumption to access; (iii) the specific qualities of the material at issue which justify sealing such material, taking into account the balance of competing interest in access; (iv) the reasons why alternatives to sealing are inadequate; and (v) whether there is consent to the motion. In addition to the motion and supporting memorandum of law, the filing Party must set out such findings in a proposed order to seal.

The Court will grant the Motion to Seal only after providing adequate notice to the public and opportunity for interested parties to object, after carefully weighing the interests advanced by the movant and those interests favoring public access to judicial documents and records, and upon finding that the interests advanced by the movant override any common law or constitutional right of public access which may attach to the information. Documents submitted under seal in accordance with this paragraph will remain under seal pending the Court's ruling. If the party desiring that the information be maintained under seal does not timely file a Motion to Seal, then the materials will be deemed unsealed, without need for order of the Court.

### **13. INADVERTENT DISCLOSURE OF PRIVILEGED MATERIAL**

(a) Pursuant to Federal Rule of Evidence 502(b), the inadvertent production or disclosure of any document or thing (including information) otherwise protected by the attorney-client privilege, work product immunity, or other privilege or immunity shall not operate as a waiver of any such privilege or immunity. Within the time period set forth below, the Producing Party who made the inadvertent production or disclosure shall send a written request to the Receiving Party, including a privilege log containing entries for each inadvertently produced document specifying, at a minimum, (a) its form (e.g., letter, memorandum, chart, etc.), (b) its general subject matter, (c) its production number ("Bates") range(s), (d) its date, (e) the full names and titles of the author(s) or

creator(s), the addressee(s) and the recipient(s), including the person(s) copied, and (f) the basis of the privilege being asserted (e.g. it shall be sufficient to state solely that the document is protected by the work product doctrine, the attorney client privilege, or other privilege or immunity), for return or destruction of the inadvertently produced or disclosed document or thing. Any request for the return or destruction of the inadvertently produced or disclosed document or thing must be made within twenty (20) days after the privileged information is used in connection with a deposition attended by the Producing Party, cited in or attached to a court filing, discovery response, or written correspondence received or sent by the Producing Party, or the Producing Party otherwise discovers that the privileged information has been produced or disclosed. Except as set forth under paragraph (a) below, within five (5) business days of receiving such a request, the Receiving Party shall return to the Producing Party or confirm in writing the destruction of all such documents and things identified by the Producing Party as being protected by the attorney-client privilege, work product immunity, or other privilege or immunity, and shall certify in writing that the Receiving Party has complied with this section.

(i) If the Receiving Party wishes to contest that any such document or thing is protected by the attorney-client privilege, work-product immunity, or other privilege or immunity, the Receiving Party shall so notify the Producing Party in writing when the document or thing is returned to the Producing Party or the Receiving Party provides notification that the document or thing has been destroyed. Should the Receiving Party elect to bring such a challenge, Outside Counsel of the Receiving Party may retain copies of the inadvertently produced document for the exclusive purpose of challenging the claim of privilege over the document and shall treat such documents as if designated CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY until the resolution of such challenge. Upon resolution of such challenge, the documents subject to the challenge shall be treated in accordance with any confidentiality designation made at the time of their

production. Outside Counsel of the Receiving Party challenging the claim of privilege shall keep only as many copies of the document as are necessary to bring such a challenge or seek relief from the Court pursuant to paragraph (ii) below.

(ii) If, within ten (10) days after the Receiving Party sends such notice of challenge to the Producing Party, the Parties are in good faith unable to resolve the dispute over the Producing Party's basis for claiming privilege, the Receiving Party may seek relief from the Court to compel production of such documents and things, the protection of which is still disputed, in accordance with the procedures set forth by the Court for such discovery disputes. If the Receiving Party is unsuccessful in challenging the claim of privilege, the Receiving Party shall destroy all copies of the inadvertently produced document.

(iii) With respect to documents and things generated by a Receiving Party, which documents and things contain information derived from such inadvertently produced documents and things, if the Receiving Party does not notify the Producing Party that the Receiving Party disputes the claims of attorney-client privilege, work-product immunity, or other privilege or immunity, or the Receiving Party is unsuccessful in challenging the claim of privilege or immunity, the Receiving Party shall either destroy the derivative documents and things or redact from them all such derivative privilege or work-product information in a manner such that the derivative information cannot in any way be retrieved or reproduced.

#### **14. INADVERTENT FAILURE TO DESIGNATE PROPERLY**

(a) The inadvertent failure by a Producing Party to designate Discovery Material as Protected Material with one of the designations provided for under this Order shall not waive any such designation provided that the Producing Party notifies all Receiving Parties that such Discovery Material is protected under one of the categories of this Order within fourteen (14) days of the Producing Party learning of the inadvertent failure to designate. The Producing Party shall reproduce



the Protected Material with the correct confidentiality designation within seven (7) days upon its notification to the Receiving Parties. Upon receiving the Protected Material with the correct confidentiality designation, the Receiving Parties shall return or securely destroy, at the Producing Party's option, all Discovery Material that was not designated properly.

(b) A Receiving Party shall not be in breach of this Order for any use of such Discovery Material before the Receiving Party receives such notice that such Discovery Material is protected under one of the categories of this Order, unless an objectively reasonable person would have realized that the Discovery Material should have been appropriately designated with a confidentiality designation under this Order. Once a Receiving Party has received notification of the correct confidentiality designation for the Protected Material with the correct confidentiality designation, the Receiving Party shall treat such Discovery Material at the appropriately designated level pursuant to the terms of this Order.

**15. INADVERTENT DISCLOSURE NOT AUTHORIZED BY ORDER**

(a) In the event of a disclosure of any Discovery Material pursuant to this Order to any person or persons not authorized to receive such disclosure under this Protective Order, the Party responsible for having made such disclosure, and each Party with knowledge thereof, shall, upon learning of the disclosure, immediately notify counsel for the Producing Party whose Discovery Material has been disclosed and provide to such counsel all known relevant information concerning the nature and circumstances of the disclosure. The responsible disclosing Party shall also promptly take all reasonable measures to retrieve the improperly disclosed Discovery Material and to ensure that no further or greater unauthorized disclosure and/or use thereof is made

(b) Unauthorized or inadvertent disclosure does not change the status of Discovery Material or waive the right to hold the disclosed document or information as Protected Material.

**16. PROSECUTION BAR**

(a) Absent written consent from the Producing Party, any individual who receives access to CONFIDENTIAL or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY information pursuant to Sections 8 and 9 above must not be involved in the prosecution of patents or patent applications for any patent asserted in this Action, any patent or application claiming priority to or sharing any priority claim with any patent asserted in this Action, or involving any pharmaceutical film formulations containing:

(1) buprenorphine for the management of pain; or

(2) buprenorphine and naloxone for the treatment of opioid addiction;

before any foreign or domestic agency, including the United States Patent Office. For purposes of this paragraph, “prosecution” means any involvement in original prosecution or reissue proceedings and, with respect to reexamination or *inter partes review* proceedings, drafting, amending, or substituting claims, advising, assisting or supervising the drafting, amending or substituting of claims for a party in this litigation. This prosecution bar shall begin when access to the Party’s Protected Material is first received by the affected individual and shall end two (2) years after final termination of this litigation, including appeals.

**17. OTHER PROCEEDINGS**

(a) By entering this order and limiting the disclosure of information in this Action, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or Party subject to this Order who becomes subject to a motion to disclose another Party’s information designated as CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY pursuant to this Order shall promptly notify that Party of the motion so that the Party may have an opportunity to appear and be heard on whether that information should be disclosed.

(b) In particular, any person or Party (the “Receiver”) subject to this Order who (a) is subpoenaed in another matter, (b) is served with a demand in another matter to which he or it is a party, or (c) is served with any other legal process by one not a party to this Action, seeking disclosure of information that is designated by another Party in this Action as CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY, shall give prompt written notice to counsel for the Producing Party within five (5) business days of receipt of such subpoena, demand, or other legal process, identifying the CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY information sought and enclosing a copy of the subpoena or legal process.

(c) The Receiver shall not produce any of the information designated CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY, unless otherwise ordered by a court of competent jurisdiction, for a period of at least fourteen (14) days after providing the required notice to the Producing Party. If, within fourteen (14) days of receiving such notice, the Producing Party gives notice to the Receiver that the Producing Party opposes production of its CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY information, the Receiver shall not thereafter produce such information until such time as the Producing Party has a reasonable opportunity to seek relief from the court. The Producing Party shall be solely responsible for asserting any objection to the requested production. Nothing herein shall be construed as requiring the Receiver or anyone else covered by this Order to challenge or appeal any order requiring production of CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY information covered by this Order, or subjecting such person to any penalties for non-compliance with any legal process or order, or to seek any further relief from this Court.

**18. PRIOR OR PUBLIC KNOWLEDGE**

This Order shall not apply to information that is or was available to the public prior to disclosure under the Order or subsequent to such disclosure. The restrictions contained in this Order shall not apply to information that is or was available to the public, whether before or after disclosure under the Order, other than by an act or omission of the Receiving Party, or that is lawfully and independently acquired from a source not subject to this Order.

**19. MATERIALS PRODUCED BY NON-PARTY**

(a) The terms of this Order, as well as the terms of any confidentiality order that may be entered into between a discovering Party and third party for the production of information to the discovering Party, are applicable to information designated CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY by a nonparty.

(b) Information provided by a non-party in connection with this Action and designated CONFIDENTIAL or HIGHLY CONFIDENTIAL - OUTSIDE COUNSEL’S EYES ONLY pursuant to the terms of this Order shall be protected by the remedies and relief provided by this Order.

**20. FINAL TERMINATION OF THIS LITIGATION**

(a) Within ninety (90) days following final termination of this litigation, including any final judgment, appeals therefrom, or settlement, unless otherwise agreed to in writing by Outside Counsel of record for the Producing Party, each Party shall assemble and return, or destroy and certify destruction of, all materials containing information designated CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY, including all copies, extracts, summaries, and derivatives thereof, to the Party from whom the designated material was obtained except that Party is not obligated to return or destroy information designated CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY that is contained on electronic

backup or archival media but which will be overwritten or destroyed in the ordinary course of business.

(b) Notwithstanding the foregoing, and subject to a continuing obligation to protect all such material pursuant to this Order, Outside Counsel may retain archive copies of filings, court papers, correspondence, deposition and trial transcripts, deposition and trial exhibits, expert reports, written discovery responses, and attorney work product (regardless of whether such materials contain or reference information designated CONFIDENTIAL, or HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY).

**21. WAIVER OR TERMINATION OF ORDER**

No part of the restrictions imposed by this Order may be waived or terminated, except by written stipulation executed by Outside Counsel of record for each Producing Party, or by an order of the Court for good cause shown. The restrictions provided for herein shall not terminate upon the conclusion of this Action, but shall continue until further order of this Court.

**22. MODIFICATION OF ORDER AND PRIOR AGREEMENTS**

This Order supersedes any agreements between the Parties regarding the confidentiality of particular information entered into before the date of this Order. However, any particular information that has been filed under seal prior to the date of this Order and provided to any Party in unredacted form, must be treated as designated as HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL’S EYES ONLY consistent with this Order.

**23. MISCELLANEOUS**

(a) Right to Further Relief. Nothing in this Order abridges the right of any person to seek its modification by the Court in the future. By stipulating to this Order, the Parties do not waive the right to argue that certain material may require additional or different confidentiality protections than those set forth herein.

(b) Termination of Matter and Retention of Jurisdiction. The terms of this Protective Order shall survive and remain in effect after the Final Determination of this Action. The Court shall retain jurisdiction after Final Determination of this Action to hear and resolve any disputes arising out of this Protective Order.

(c) Successors. This Order shall be binding upon the Parties hereto, their attorneys, and their successors, executors, personal representatives, administrators, heirs, legal representatives, assigns, subsidiaries, divisions, employees, agents, retained consultants and experts, and any persons or organizations over which they have direct control.

(d) Right to Assert Other Objections. By abiding by the terms of this Protective Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order. This Order shall not constitute a waiver of the right of any Party to claim in this action or otherwise that any Discovery Material, or any portion thereof, is privileged or otherwise non-discoverable, or is not admissible in evidence in this Action or any other proceeding.

(e) Burdens of Proof. Notwithstanding anything to the contrary above, nothing in this Protective Order shall be construed to change the burdens of proof or legal standards applicable in disputes regarding whether particular Discovery Material is confidential, which level of confidentiality is appropriate, whether disclosure should be restricted, and if so, what restrictions should apply.

(f) Modification by Court. This Order is subject to further court order based upon public policy or other considerations, and the Court may modify this Order *sua sponte* in the interests of justice. The United States District Court for Eastern District of North Carolina is responsible for the interpretation and enforcement of this Order. All disputes concerning Protected Material,

however designated, produced under the protection of this Order shall be resolved by the United States District Court for the Eastern District of North Carolina.

(g) Discovery Rules Remain Unchanged. Nothing herein shall alter or change in any way the discovery provisions of the Federal Rules of Civil Procedure, the Local Rules for the United States District Court for Eastern District of North Carolina, or the Court's own orders. Identification of any individual pursuant to this Protective Order does not make that individual available for deposition or any other form of discovery outside of the restrictions and procedures of the Federal Rules of Civil Procedure, the Local Rules for the United States District Court for Eastern District of North Carolina, or the Court's own orders.

(h) Section Captions. The title captions for each section of this Confidentiality Order are for convenience only and are not intended to affect or alter the text of the sections or the substance of the Order.

Dated: July 26, 2021

A handwritten signature in black ink, reading "Robert T. Numbers, II". The signature is written in a cursive, flowing style. Below the signature is a horizontal line.

Robert T. Numbers, II  
United States Magistrate Judge

**EXHIBIT A**

**IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF NORTH CAROLINA  
WESTERN DIVISION**

INDIVIOR INC. *f/k/a* RECKITT BENCKISER  
PHARMACEUTICALS INC., and  
AQUESTIVE THERAPEUTICS, INC. *f/k/a*  
MONOSOL RX, LLC,

Plaintiffs,

v.

BIODELIVERY SCIENCES  
INTERNATIONAL, INC.,

Defendant

Civil Action No. 5:19-CV-505-D

**ACKNOWLEDGEMENT OF PROTECTIVE ORDER  
AND AGREEMENT TO BE BOUND**

I, \_\_\_\_\_ [print or type full name], of  
\_\_\_\_\_  
\_\_\_\_\_  
[print or  
type full address], declare under penalty of perjury that I have read in its entirety and understand the  
Protective Order that was issued by the United States District Court for the Eastern District of North  
Carolina on \_\_\_\_\_ in the case identified above.

I agree to comply with and to be bound by all the terms of this Protective Order and I  
understand and acknowledge that failure to so comply could expose me to sanctions and punishment  
in the nature of contempt. I solemnly promise that I will not disclose in any manner any information  
or item that is subject to this Protective Order to any person or entity except in strict compliance with  
the provisions of this Order. I also agree to notify any stenographic or clerical personnel who are



required to assist me of the terms of this Order.

I understand that I am to retain all copies of any Protected Material, however designated, in a secure manner, and that all copies are to remain in my personal custody until I have completed my assigned duties, whereupon the copies and any writings prepared by me containing any information designated as Protected Material are to be returned to counsel who provided me with such material or destroyed, with certification of destruction.

I further agree to submit to the jurisdiction of the United States District Court for the Eastern District of North Carolina for the purpose of enforcing the terms of this Protective Order, even if such enforcement proceedings occur after termination of this Action.

Date: \_\_\_\_\_

Printed name: \_\_\_\_\_

Signature: \_\_\_\_\_